UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,372	04/19/2006	Mara Rossi	SER-107	9428

23557 7590 07/06/2009

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO Box 142950
GAINESVILLE, FL 32614

EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,372	ROSSI ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25,32-34 and 38-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25,32-34 and 38-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 21 April 2009 has been entered in full. Claims 1-21, 26-31, and 35-37 have been cancelled and claim 1 has been amended. Claims 47-49 have been added.

Claims 22-25, 32-34, 38-49 are under examination.

Claim Objections

Claim 41 is objected to because of the following informalities:

Claim 41 uses acronym without first defining what they represent in the independent claims (see for example, "TMAE"). While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Appropriate correction is required.

Rejection Withdrawn

35 USC § 103

Applicant's response and amendments made to claim 22 filed on 04/21/2009 have overcome the rejection of claims 22-25, 38, 39, 42, 43, and 44 under 35 USC 103(a). Applicants have added the limitations reciting "*equilibrated to a pH of 6.1+/- 0.1 with a buffer*" and "*from said hydrophobic charge-induction chromatograph resin with a buffer having a pH of 8.4 +/- 0.1*". The references of Boschetti, Xiang, and Burton do teach or suggest the newly added limitations. The rejection of claims 22-25, 38, 39, 42, 43, and 44 under 35 USC 103(a) has been withdrawn.

New Ground of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> This application currently names joint inventors.

In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The newly added claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti E. (2002, TRENDS in Biotechnology, Volume 20, Issue 8, pages 333-337) in view of Xiang et al. (2001, The Journal of Biological Chemistry, Volume 276, Issue 20, pages 17380-17386) and Burton et al. (1998, Journal of Chromatography A, Volume 814, pages 71-81).

The invention is drawn to a process for the production of purified interleukin-18 binding protein (IL-18BP) comprising loading a fluid selected from urine or cell culture supernatant and containing IL-18BP onto a hydrophobic charge-induction chromatography resin, eluting the IL-

18BP from said hydrophobic charge-induction chromatography resin and one or more ultrafiltration steps.

The teachings of Boschetti (2002), Xiang (2001), and Burton (1998) have been disclosed at pages 3-6 of the office action mailed 01/22/2009 and at pages 8-9 of the Office action mailed 10/09/2007. However, neither references by Boschetti, Xiang, and Burton teach any additional ultrafiltration steps.

Under *KSR*, it's now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated. When there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try may show that it was obvious under § 103 (*KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007)).

Based on the disclosure of Boschetti, Xiang, Burton, and the general knowledge of skill in the art, it would have been obvious to a process for the production of purified interleukin-18 binding protein (IL-18BP) comprising loading a fluid selected from urine or cell culture supernatant and containing IL-18BP onto a hydrophobic charge-induction chromatography resin, eluting the IL-18BP from said hydrophobic charge-induction chromatography resin (see pages 3-6 of the office action mailed 01/22/2009 and at pages 8-9 of the Office action mailed 10/09/2007).

In addition, it would have been obvious for one skilled in the art to modify the process for the production of purified interleukin-18 binding protein (IL-18BP) as taught by Boschetti, Xiang, and Burton by adding one or more ultrafiltration steps. One of ordinary skill in the art at the time the invention was made would have been motivated to add one or more ultrafiltration steps to

the process of purification of IL-18BP and because "a person of ordinary skill has good reason to pursue the know options within is or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

In addition, one of skill in the art would have been motivated to add one or more ultrafiltration steps to the purification process of IL-18BP because the additional purification step would increase the purity of IL-18BP and the effectiveness and the biological activity of the purified IL-18 BP.

Accordingly, the invention taken as a whole is prima facie obvious.

Conclusion

Claims 22-25, 32-34, 38-46, 48, and 49 are allowed. Claim 47 is not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
June 30, 2009

/Robert Landsman/
Primary Examiner, Art Unit 1647